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Practitioner's Docket No. 1030.004 *PATENT*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of: Snyder et al. Group No. 1611

Application No.: 10/821,745 Examiner: Ghali, Isis

Filed: April 9, 2004 Conf. 1863

For: SUSTAINED RELEASE SURGICAL DEVICE AND METHOD OF MAKING AND USING THE SAME

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

This is an Appeal Brief under 37 C.F.R. § 41.37 appealing the Final Rejection of claims in the above-referenced patent application, which were rejected in an Office Action dated May 25, 2010 and an advisory action mailed on August 06 , 2010. Each of the topics required by 37 C.F.R. § 41.37 are presented in this Brief and are labeled appropriately.

I. Real party in interest

The real parties in interest are the inventors.

II. Related appeals and interferences

There are no appeals or interferences related to the present application of which the Appellants are aware.

III. Status of claims

Claims 11 and 21 to 39 are pending in this application; claims 1 to 10 and 12 to 20 have been cancelled. The rejection of claims 11 and 21 to 39 are hereby appealed. Appellants respectfully request an indication of allowability of claim 11 and its dependents, claims 21 to 39, or at least the reversal of the obviousness rejection of claim 11 and its dependents, claims 21 to 39.

IV. Status of Amendments

No amendments are pending.

V. Summary of claimed subject matter

In this summary of the claims, no line numbers are used because no line numbering is used in the specification (only paragraph numbering).

The present claimed application relates to a glaucoma shunt device that is implanted in an eye and aids the eye in reaching a desired intraocular pressure, while also providing an erodable sustained release medium that assists in treatment. The erosion helps to dynamically achieve the desired ocular pressure. Claim 11 is an implantable device, comprising: an implantable elongated hollow glaucoma drainage tube including a solid walled plastic lumen having a lumen section that extends into the eye and wraps generally circularly around the cornea and includes a flow passage so that when the tube is implanted within an eye the tube has a first end located in a first portion of an eye and a second end located in a second portion of the eye and the flow passage spans between the first end and the second end; and a sustained release medium including caprolactone and an antimicrobial within the interior of the lumen that is filled with the sustained release medium to define a head space passage that increases its degree of opening over time as matter is passed through the lumen; wherein the lumen has a circular cross section fixed inner and outer dimension, defining a lumen diameter, the tube includes a plurality of openings of a fixed size and shape, through which the sustained release medium escapes, and the sustained release medium comprises a solid material. Page 1, Paragraphs 0010 to 0012; Page 3, Paragraphs 0042 to 0044; Page 4, Paragraphs 0050 and 0053; and Figures 1, 5, and 7.

Claim 21 adds the feature that the lumen has open ends. Page 3, Paragraphs 0044 and 0049 and Figures 4 and 5.

Claim 22 adds the features that the device further comprises a radiological detectable marker that are monitored to correlate the reduction of the size of a wound site or a mass under consideration. Page 4 Paragraph 0056.

Claim 23 adds the feature where the sustained release material is provided as layers. Page 4, Paragraph 0057.

Claim 24 adds the feature further comprise a coating of the sustained release material on an exterior of the lumen and and covering the openings, so that as a layer diminishes, the openings of the lumen become exposed and thereby provides gradually increasing volumes or areas through which the sustained release material that is filled within the lumen escapes from

the lumen. Page 3, Paragraph 0044.

Claim 25 adds the feature wherein the first end when implanted is located in the anterior chamber of the eye or in the pars plana portion of the eye. Page 3, Paragraph 0043.

Claim 26 add the feature that the lumen has open ends. Page 3, Paragraphs 0044 and 0049 and Figures 4 and 5.

Claim 27 adds the features that the device further comprises a radiological detectable marker that are monitored to correlate the reduction of the size of a wound site or a mass under consideration. Page 4 Paragraph 0056.

Claim 28 adds the features that the device further comprises a radiological detectable marker that are monitored to correlate the reduction of the size of a wound site or a mass under consideration. Page 4 Paragraph 0056.

Claim 29 adds the feature where the sustained release material is provided as layers. Page 4, Paragraph 0057.

Claim 30 adds the feature where the sustained release material is provided as layers. Page 4, Paragraph 0057.

Claim 31 adds the feature where the sustained release material is provided as layers. Page 4, Paragraph 0057.

Claim 32 adds the feature further comprising a coating of the sustained release material on an exterior of the lumen and and covering the openings, so that as a layer diminishes, the openings of the lumen become exposed and thereby provides gradually increasing volumes or areas through which the sustained release material that is filled within the lumen escapes from the lumen. Page 3, Paragraph 0044.

Claim 33 adds the feature further comprising a coating of the sustained release material on an exterior of the lumen and and covering the openings, so that as a layer diminishes, the openings of the lumen become exposed and thereby provides gradually increasing volumes or areas through which the sustained release material that is filled within the lumen escapes from the lumen. Page 3, Paragraph 0044.

Claim 34 adds the feature further comprising a coating of the sustained release material on an exterior of the lumen and and covering the openings, so that as a layer diminishes, the openings of the lumen become exposed and thereby provides gradually increasing volumes or areas through which the sustained release material that is filled within the lumen escapes from the lumen. Page 3, Paragraph 0044.

Claim 35 adds the feature further comprising a coating of the sustained release material on an exterior of the lumen and and covering the openings, so that as a layer diminishes, the openings of the lumen become exposed and thereby provides gradually increasing volumes or areas through which the sustained release material that is filled within the lumen escapes from the lumen. Page 3, Paragraph 0044.

Claim 36 adds the feature wherein the erosion of the layers is halted when a desired intraocular pressure is reached. Page 3, Paragraph 0046.

Claim 37 adds the feature wherein the erosion of the layers is halted when a desired intraocular pressure is reached. Page 3, Paragraph 0046.

Claim 38 adds the feature wherein the device includes a focal surrounding element that can be altered to shrink and constrict the lumen. Page 3, Paragraph 0047.

Claim 39 add the feature wherein the device includes a focal surrounding element that can be altered to shrink and constrict the lumen. Page 3, Paragraph 0047.

VI. Grounds of rejection to be reviewed on appeal

The grounds of rejection to be reviewed on appeal are the following:

Claims 11 and 21, 24-26, 32, 33, and 38 are rejected under 35 U.S.C. § 103 as being unpatentable over Smedley U.S. Patent No. 7,163,543 (hereinafter Smedley) in combination with Peyman U.S. Patent No. 7,354,574 (hereinafter Peyman).

Claims 22, 27, and 28 are rejected under 35 U.S.C. § 103 as being unpatentable over Smedley and Peyman and further in view of Bardenstein U.S. Patent No. 4,743,255 (hereinafter Bardenstein).

Claims 23, 29-31, 34-37, and 39 are rejected under 35 U.S.C. § 103 as being unpatentable over Smedley and Peyman and further in view of Wong U.S. Patent No. 6,692,759 (hereinafter Wong) as applied to claims 23, 29-30, 36, and over the combination of Smedley, Peyman, and Bardenstein futher in view of Wong as applied to claims 31, 34-35, 37, and 39.

As explained in the reasons set forth in the Argument section below, Applicants respectfully request reversal of the obviousness rejection.

Arguments

Summary of Arguments:

A. **The office action has not presented any fact findings as to where the teachings of Smedley and Peyman disclose the following elements of claims 11, 24, and 32 to 33.** No facts have been cited showing where the cited references disclose the following underlined portions:

> An implantable device, comprising: an implantable elongated hollow glaucoma drainage tube including a solid walled plastic lumen having a lumen section that extends into the eye and wraps generally circularly around the cornea and includes a flow passage so that when the tube is implanted within an eye the tube has a first end located in a first portion of an eye and a second end located in a second portion of the eye and the flow passage spans between the first end and the second end; and a sustained release medium including caprolactone and an antimicrobial within the interior of the lumen that is filled with the sustained release medium to define a head space passage that increases its degree of opening over time as matter is passed through the lumen.

The office action has further failed to present any fact findings as to where Smedley and Peyman teach the underlined portion of claims 24 and 32 to 34, which state:

> a coating of the sustained release material on an exterior of the lumen and covering the openings, so that as a layer diminishes the openings of the lumen become exposed and thereby provides gradually increasing volumes or areas through which the sustained release medium that is filled within the lumen escapes from the lumen.

B. **The office action has not presented any fact findingss as to where the teachings of Smedley, Peyman, Bardenstein, and further in view of Wong disclose the following underlined elements of claims 34 to 37.** No facts have been presented as to where Smedley, Peyman, Bardenstein, and further in view of Wong teach claim 34, which states:

> a coating of the sustained release material on an exterior of the lumen and covering the openings, so that as a layer diminishes the openings of the lumen become exposed and thereby provides gradually increasing volumes or areas through which the sustained release medium that is filled within the lumen escapes from the lumen.

The office action has further failed to present any fact findings as to where Smedley, Peyman, Bardenstein, and further in view of Wong teach claims 36 and 37, which state, "wherein the erosion of the layers is halted when a desired intraocular pressure is reached."

C. **The absence of fact finding precludes a proper analysis under KSR from which to conclude that the combination is obvious.** In view of the absence of fact findings a proper analysis under KSR was not performed. By way of example, no analysis shows how any of the structures in the prior art have a head space that increases over time, as is found in claim 11.

D. **"The proposed modification cannot render the prior art unsatisfactory for its intended purpose." MPEP 2143.01V.** The modification proposed in the office action that allegedly renders claims 38 and 39 obvious is believed to render Smedley unsatisfactory for its intended purpose.

The Claims do not stand and fall together. Appellants respectfully request that the following claims sets be considered separately. Claim 11 should be considered separately. Claims 21 to 23 should be considered together. Claim 24 should be considered separately. Claims 23 and 36 should be considered together. Claims 25, 27, and 29 should be considered together. Claims 26, 28, 30, and 31 should be considered together. Claim 32 should be considered separately. Claim 33 should be considered separately. Claim 34 should be considered separately. Claim 35 should be considered separately. Claim 36 should be considered separately. Claim 37 should be considered separately. Claim 38 should be considered separately. Claim 39 should be considered separately. Applicants respectfully request that the claims be considered separately for the reasons stated hereinafter.

The Law

The Examination of Patent applications imposes certain statutory obligations upon the Examiner, as set forth in 35 U.S.C. 132,

> Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and

references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. (emphasis added)

KSR does not impact *Graham v. John Deere*, 383 U.S. 1 (1966), which still imposes upon the Office the burden to make certain factual findings underlying a determination of obviousness, including the scope and content of the prior art.

Since the Supreme Court's decision in *KSR v. Teleflex*[1] the key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court, quoting *In re Kahn*[2], stated that

> "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" [3]

Also, as stated in the USPTO Examination Guidelines[4],

> "Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art."

According to the USPTO Examination Guidelines and its citing of *KSR*,

> "The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention. "'[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.'"[5] If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art."[6]

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[1] *KSR v. Teleflex*, 82 USPQ2d 1385 (2007).
[2] 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).
[3] *KSR*, 82 USPQ2d 1385, 1396, emphasis added.
[4] Federal Register / Vol. 72, No. 195 / Wednesday, October 10, 2007 / Notices page 57528, emphasis added.
[5] *KSR*, 82 USPQ2d 1385, 1396.
[6] Federal Register / Vol. 72, No. 195 / Wednesday, October 10, 2007 / Notices page 57529

Arguments

A. **The office action has not presented any fact findings as to where the teachings of Smedley and Peyman disclose the following elements of claims 11, 24, and 32 to 33.** No facts have been cited showing where the cited references disclose the following underlined portions:

> An implantable device, comprising: an implantable elongated hollow glaucoma drainage tube including a solid walled plastic lumen having a lumen section that extends into the eye and wraps generally circularly around the cornea and includes a flow passage so that when the tube is implanted within an eye the tube has a first end located in a first portion of an eye and a second end located in a second portion of the eye and the flow passage spans between the first end and the second end; and a sustained release medium including caprolactone and an antimicrobial within the interior of the lumen that is filled with the sustained release medium to define a head space passage that increases its degree of opening over time as matter is passed through the lumen.

The office action has further failed to present any fact findings as to where Smedley and Peyman teach the underlined portion of claims 24 and 32 to 34, which state:

> a coating of the sustained release material on an exterior of the lumen and covering the openings, so that as a layer diminishes the openings of the lumen become exposed and thereby provides gradually increasing volumes or areas through which the sustained release medium that is filled within the lumen escapes from the lumen.

The rejection under 35 U.S.C. § 103 is defective because the office action does not specifically and clearly disclose where these required elements of the claims are located in the cited references. Applicants believes that the Office Action did not set forth an appropriate analysis to satisfy the Supreme Court's requirements from *KSR International co. v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1396 (2007). The Office has the burden to explicitly analyze:

> . . . interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated

reasoning with some rational underpinning to support the legal conclusion of obviousness")....

The Final rejection in rejection paragraph 4 does not establish a case of prima facie obviousness because no facts have been presented in the Final Rejection showing that the primary references Smedley or Peyman teach or suggest a "lumen section that extends into the eye and wraps generally circularly around the cornea." The Final Office action does not even state these words in rejection paragraph 4, thus, a prima facie obviousness rejection cannot be present in the Final Rejection.

The office action in "Response to Arguments" paragraph 7 alleges that claim 11 is obvious in view of Smedley and Peyman in view of MPEP § 2144.04(IV)(B) and *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). Appellants respectfully disagree that claim 11 is obvious in view of Smedley and Peyman in view of *Dailey*. In *Dailey*, the court discusses two prior art references for a nursing container. The court states that, "one of ordinary skill in the art would find it obvious to use the slit nipple of Blanchett in the collapsible container of Matzen in order to achieve intermittent flow responsive to sucking." The court after performing this fact finding presents evidence to support the fact finding. The facts and evidence show where every element of the claim was taught by a prior art reference and the court concludes that it would have been obvious for one skilled in the art to have combined Blanchett and Matzen to arrive at the claimed invention. The Final Rejection has **neither** performed the requisite fact finding that the court performed in *Dailey* **nor** presented facts showing the claimed feature. The office action has not presented any facts as to where any reference teaches "a lumen section that extends into the eye and wraps generally circularly around the cornea." Without performing the required fact finding the office action cannot come to the conclusion that claim 11 is obvious. Furthemore, ("'[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness'")... *KSR International co. v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1396 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)).

As previously stated, the Final Rejection paragraph 4 did not even include the discussion of *Dailey*. This discussion was added in the Response to Arguments paragraph 7 to bolster the rejection, which further supports Appellants assertion that the necessary fact finding was not

performed. Response to Arguments paragraph 7, states:

> Regarding the limitation of "lumen wraps generally circularly around the cornea, as instantly recited by amended claim 11, applicants failed to show unexpected results obtained from this limitation over the prior art stent that effectively treats glaucoma by directed the aqueous flow out of the anterior chamber of the eye through a stent to Schlem's canal, as applicants have done. MPEP §2144.04 (IV)(B) similarly states that simply changing the shape of a device was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed invention was significant. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) Such is expressly evident in prior art teachings of figure 3 of stent that can have different shape to accommodate between the anterior chamber and Schlem's canal.

The Final Rejection assumes that every element of the claimed invention has been presented, and attempts to improperly shift the burden to Appellants, without actually presenting facts that are supported by evidence found in the references of record. The addition of *Dailey* does not create a proper prima facie obviousness rejection, as is discussed above, because the court in *Dailey* presented facts as to where every element of the claimed invention may be found in the references of record—which has not been performed for the present invention. The Advisory Action dated August 6, 2010 again does not present any facts as to where this element of claim 11 is taught, and completely ignores the arguments presented by Appellants.

Furthermore, Appellants do not necessarily agree with the assertion that *In re Dailey* affirmatively stands for the premise that "simply changing the shape of a device was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed invention was significant."

The Final Office action further failed to present any facts as to where either Smedley or Peyman teaches an additional element of claim 11, which states, "the interior of the lumen that is filled with the sustained release medium to define a head space passage."

The office action merely states:

Regarding the limitation of increase of the degree of opening of the head space passage as claimed by claim 11, 24, 32-33, and halting the eroded layers when the pressure is released, the combined teaching of Smedley and Peyman provides glaucoma drainage tube having in the interior a polymer composition comprising caprolactone, and it is expected that caprolactone will be eroded slowly to release the therapeutic agent, and bidegradation of the caprolactone will halt the erosion product, therefore forming the head space passage as the polymer degrades, and it is expected that by time and with erosion of the caprolactone matrix, more space is created in the stent lumen.

Appellants believe that no facts have been provided in rejecting this claimed element. For example, does Smedley or Peyman teach these limitations? Where can these limitations be found in either reference? Appellants believe that this rejection is merely a conclusory statement that is not supported by any facts or evidence as required under the law. Without presenting facts supported by evidence Appellants do not believe that a proper prima facie obviousness has been presented.

Rejection paragraph 4 next alleges that claims 24 and 32-34 are taught by Smedley; however, the office action has failed to present any fact findings as to where Smedley teaches a coating that covers the openings in the lumen. The Final Rejection in rejection paragraph 4 states:

surrounding the device (col.10, lines 31-38, 60-65). The coating is expected to cover the openings as required by claims 24, 32-34. The teaching of the reference that "the

therapeutic agent can be loaded in interior location of the stent", would have suggested inner surface of the lumen of the stent or within the wall. Regarding claim 38, Smedley teaches, in col.9, lines 36-46, flow restricted member that can be a polymer that reads on claim 38.

The Final Rejection in reference to covering the openings states that "[t]he coating is expected to cover the openings." (Emphasis Added) The word expected indicates that the office action could not find any factual support showing where the references of record teach "covering the openings." The office action has the burden to show where every element of the claims is taught either expressly or inherently by the references of record. A mere conclusory statement does not create a proper prima facie obviousness rejection and Applicants respectfully request that the rejection be withdrawn. ("'[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness'")…. *KSR International co. v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1396 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)).

In view of the lack of fact finding supported by substantial evidence, the Final Rejection does not establish a case of prima facie obviousness and the evidence instead points to the unobviousness of the claimed invention. Therefore, rejection paragraph 4 of the final office action does not sustain the alleged rejections and the rejections cannot be maintained as to claims 11, 24, and 32 to 33, and Applicants respectfully request that the board withdraw the rejections.

B. **The office action has not presented any fact findings as to where the teachings of Smedley, Peyman, Bardenstein, and further in view of Wong disclose the following underlined elements of claims 34 to 37.** No facts have been presented as to where Smedley, Peyman, Bardenstein, and further in view of Wong teach claim 34, which states:

> a coating of the sustained release material on an exterior of the lumen and covering the openings, so that as a layer diminishes the openings of the lumen become exposed and thereby provides gradually increasing volumes or areas

through which the sustained release medium that is filled within the lumen escapes from the lumen.

The office action has further failed to present any fact findings as to where Smedley, Peyman, Bardenstein, and further in view of Wong teach claims 36 and 37, which state, "wherein the erosion of the layers is halted when a desired intraocular pressure is reached."

Foremost, the rejection of these claims is abundantly unclear. The rejection states:

6. Claims 23, 29-31, 34-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Smedley and Peyman and further in view of Wong et al. (US 6,692,759 previously recited) as applied to claims 23, 29-30, 36, and over the combination of Smedley, Peyman and Bardenstein and further in view of Wong et al. as applied to claims 31, 34-35, 37 and 39.

This rejection does not appear to be proper as the office action alleges that claims 23, 29-31, 34-37, and 39 are rejected in view of the rejections to 23, 29-30, and 36, and further in view of claims 31, 34-35, 37, and 39. Appellants do not understand how this set of claims is rejected in view of itself; therefore, Appellants do not believe a proper rejection has been set forth in the Final Rejection.

Furthermore, despite the lack of clarity in the rejections the Final Rejection does not set forth the requisite fact findings. No facts have been alleged in rejection paragraph 6 regarding claims 34 and 35. Rejection Paragraph 6 does not mention claims 34 and 35 or their claim language within this paragraph other than listing claims 34 and 35 in the heading of rejection paragraph 6. Appellants maintain that no facts have been provided showing were Smedley and Peyman teach this claimed element, as has previously discussed in section A, and rejection paragraph 6 has not presented any new facts illustrating where Bardenstein or Wong cure these defects; thus, a prima facie obviousness rejection has not been presented as to claims 34 and 35.

The office action further alleges that claims 36 and 37 are taught by the references of record, but the office action only lists the claims in the heading of rejection paragraph 6. Claims 36 and 37 state, "wherein the erosion of the layers is halted when a desired intraocular pressure is reached." The office action does not provide any facts as to where any reference of record

teaches claims 36 and 37. Without these facts a prima facie obviousness rejection cannot be sustained, and Appellants respectfully request that these rejections be withdrawn.

C. **The absence of fact finding precludes a proper analysis under KSR from which to conclude that the combination is obvious.** In view of the absence of fact findings a proper analysis under KSR was not performed. By way of example, no analysis shows how any of the structures in the prior art have a head space that increases over time, as is found in claim 11.

As has been previously pointed out, the office action has failed to perform fact findings that are supported by substantial evidence for all of the rejections. Moreover, the office action has not presented evidence that all of the claims are obvious in view of the references of record and that the references are combinable.

Under *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007) in light of *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), Applicants believe that a proper 35 U.S.C. § 103 rejection was not made. Although the teaching-suggestion-motivation (TSM) test requirements as applied in *KSR* have been altered to be applied in a less rigid manner, the references still are not combinable. The Court in KSR said:

> Often, it will be necessary...to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an **apparent reason** to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis **should be made explicit**.

KSR, 82 USPQ2d at 1395 (emphasis added). Even under *KSR* where the TSM test is applied less rigidly: (1) these four cited references are in dispute with each other, (2) no Teaching Suggestion or Motivation to combine these reverences has been provided, (3) there was no apparent reason to combine the elements, and (4) no explicit analysis was made showing why these references are combinable. Moreover, the office action has not shown where any of these references teach: "having a lumen section that extends into the eye and wraps generally circularly around the cornea, a solid walled plastic lumen, and a lumen has open ends"; "the interior of the lumen that is filled with the sustained release medium to define a head space passage"; "a coating of the sustained release material on an exterior of the lumen and covering the openings"; and "wherein the erosion of the layers is halted when a desired intraocular

pressure is reached." If no fact findings have been performed regarding an element then no apparent reason can be provided for combining that element under KSR, and a proper prima facie obviousness rejection cannot be made. Applicants believe that the proper fact findings have not been performed and that the rejection is improper. Therefore, Applicants respectfully request that the rejection be withdrawn.

D. **"The proposed modification cannot render the prior art unsatisfactory for its intended purpose." MPEP 2143.01V.** The modification proposed in the office action that allegedly renders claims 38 and 39 obvious is believed to render Smedley unsatisfactory for its intended purpose.

The office action alleges in rejection paragraph 4 that Smedley teaches claim 38; however, Applicants do not believe that the facts as alleged are supported by the evidence found in Smedley. Claim 38 states, "wherein the device includes a focal surrounding element that can be altered to shrink and constrict the lumen." The office action cites col. 9, lines 36-46 which states,

In modified embodiments, the flow-restricting member **72** (FIG. **5**) may be situated in any location within the device **31** and/or **31**A such that blood flow is restricted from retrograde motion. More than one flow-restricting member **72** mat also be efficaciously used, as needed or desired. The flow-restricting member **72** may, in some embodiments, be a filter made of a material selected from the following filter materials: expanded polytetrafluoroethylene, cellulose, ceramic, glass, Nylon, plastic, and fluorinated material such as polyvinylidene fluoride ("PVDF") (trade name: Kynar, by DuPont), and combinations thereof.

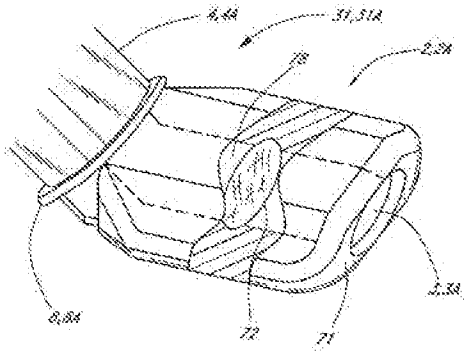

FIG. 5

This passage states that the "flow restricting member 72 (FIG. 5) may be situated in any location within the device." (emphasis added) Claim 38 claims "a focal surrounding element that can be altered to shrink and constrict the lumen." Appellants do not believe that the flow restricting device will be able to shrink and constrict the lumen from the inside of the lumen. Furthermore, if the flow-restricting member shrinks Appellants do not believe that it will be able to "restrict[] retrograde motion [of blood flow]." If the flow restrictor is no longer able to restrict retrograde motion of blood flow then the proposed modification will render the prior art unsatisfactory for its intended purpose in violation of MPEP 2143.01V. Furthermore, if the flow restricting member shrinks, the flow restricting member will restrict less blood flow, which performs exactly the

opposite function that is described in the passage cited by the Final Rejection. A response to these arguments was issued in the advisory action dated August 6, 2010 and state:

> In response to this argument, it is argued that Smedley teaches, in col 9, lines 36-46, flow restricted member that can be a polymer that reads on claim 38. The claim does not recite any more specification of the flow restricting member. Further, the present claims are directed to a product, and the elements of the product are taught by the prior art in combination. The intended function of part of the device does not impart patentability to the claims.

This response does not address the issues raised by Appellants. For example, how does the "flow restricting member 72" "shrink and constrict the lumen"? How does the "flow restricting member 72" shrink and constrict the lumen from "within" the device? How does the "flow restricting member 72" shrink "such that blood flow is restricted from retrograde motion"? Without the Final Rejection being able to answer these questions Appellants believe that the proposed modification renders the Smedley unsatisfactory for its intended purpose.

The office action allegedly rejected claim 39 in rejection paragraph 6; however, the language of claim 39 was never referred to in rejection paragraph 6. The Final Rejection did not present any facts showing where the language of claim 39 is found in Bardenstein or Wong. Furthermore, the Final Rejection did not present any additional facts or evidence explaining how these references cure the defects described herein for claim 38. Therefore, Applicants do not believe that a proper prima facie obviousness rejection has been presented by the office action, and Applicants respectfully request that the rejection be withdrawn.

VII. Claims Appendix

Claim 11 An implantable device, comprising:

a) an implantable elongated hollow glaucoma drainage tube including a solid walled plastic lumen having a lumen section that extends into the eye and wraps generally circularly around the cornea and includes a flow passage so that when the tube is implanted within an eye the tube has a first end located in a first portion of an eye and a second end located in a second portion of the eye and the flow passage spans between the first end and the second end; and

b) a sustained release medium including caprolactone and an antimicrobial within the interior of the lumen that is filled with the sustained release medium to define a head space passage that increases its degree of opening over time as matter is passed through the lumen;

wherein the lumen has a circular cross section fixed inner and outer dimension, defining a lumen diameter, the tube includes a plurality of openings of a fixed size and shape, through which the sustained release medium escapes, and the sustained release medium comprises a solid material.

Claim 21 The device of claim 11, wherein the lumen has open ends.

Claim 22 The device of claim 11, further comprising a radiological detectable marker that are monitored to correlate with the reduction of the size of a wound site or a mass under consideration.

Claim 23 The device of claim 11, where the sustained release material is provided as layers.

Claim 24 The device of claim 21, further comprising a coating of the sustained release material on an exterior of the lumen and covering the openings, so that as a layer diminishes, the openings of the lumen become exposed and thereby provides gradually increasing volumes or areas through which the sustained release material that is filled within the lumen escapes from the lumen.

Claim 25 The device of claim 11, wherein the first end when implanted is located in the anterior chamber of the eye or in the pars plana portion of the eye.

Claim 26 The device of claim 25, wherein the lumen has open ends.

Claim 27 The device of claim 25, further comprising a radiological detectable marker that are monitored to correlate with the reduction of the size of a wound site or a mass under consideration.

Claim 28 The device of claim 26, further comprising a radiological detectable marker that are monitored to correlate with the reduction of the size of a wound site or a mass under consideration

Claim 29 The device of claim 25, where the sustained release material is provided as layers.

Claim 30 The device of claim 26, where the sustained release material is provided as layers.

Claim 31 The device of claim 27, where the sustained release material is provided as layers.

Claim 32 The device of claim 25, further comprising a coating of the sustained release material on an exterior of the lumen and covering the openings, so that as a layer diminishes, the openings of the lumen become exposed and thereby provides gradually increasing volumes or areas through which the sustained release material that is filled within the lumen escapes from the lumen.

Claim 33 The device of claim 26, further comprising a coating of the sustained release material on an exterior of the lumen and covering the openings, so that as a layer diminishes, the openings of the lumen become exposed and thereby provides gradually increasing volumes or areas through which the sustained release material that is filled within the lumen escapes

from the lumen.

Claim 34 The device of claim 28, further comprising a coating of the sustained release material on an exterior of the lumen and covering the openings, so that as a layer diminishes, the openings of the lumen become exposed and thereby provides gradually increasing volumes or areas through which the sustained release material that is filled within the lumen escapes from the lumen.

Claim 35 The device of claim 31, further comprising a coating of the sustained release material on an exterior of the lumen and covering the openings, so that as a layer diminishes, the openings of the lumen become exposed and thereby provides gradually increasing volumes or areas through which the sustained release material that is filled within the lumen escapes from the lumen.

Claim 36 The device of claim 23, wherein the erosion of the layers is halted when a desired intraocular pressure is reached.

Claim 37 The device of claim 35, wherein the erosion of the layers is halted when a desired intraocular pressure is reached.

Claim 38 The device of claim 11, wherein the device includes a focal surrounding element that can be altered to shrink and constrict the lumen.

Claim 39 The device of claim 35, wherein the device includes a focal surrounding element that can be altered to shrink and constrict the lumen.

VIII. Evidence appendix

None

IX. Related proceedings appendix

None.

X. Conclusions

It is respectfully submitted that, based upon the above, the combinations of Smedley, Peyman, Bardenstein, and Wong do not render the subject matter of claims 11 and 21 to 39 obvious. Appellants respectfully request an indication of allowablity for claim 11 and its dependents claims 21 to 39, or at least a reverasal of the obviousness rejection of claim 11 and its dependents, claims 21 to 39.

If for some reason Applicant has not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent the abandonment of this application, please consider this as a request for an extension for the required time period and/or authorization to charge our Deposit Account No. 50-1097 for any fee which may be due.

Respectfully submitted,

Dated: Dec. 17, 2010

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